IVAC® PCAM® Syringe Pump

Directions For Use - English

CardinalHealth

CE 0086

Contents

Introduction

The IVAC® PCAM® Syringe Pump (herein after referred to as "pump") system allows a patient to maintain a consistent level of pain relief by providing self administration of a clinician-prescribed dose of analgesic as and when it is required.

When the hand set is operated and the demand is within the parameters set by the clinician, the pump will automatically administer a precise bolus dose of analgesic.

For enhanced monitoring and management of post operative acute pain within the hospital, the pump provides convenient Patient Controlled Analgesia (PCA) and detailed information at the bed-side about the patients use of PCA.

Central to an effective pain service, the pump promotes improved pain management, more effective use of nursing resources, provides patient comfort and can contribute towards a quicker recovery.

Intended Use:

The pump is designed to meet the infusion requirements within the operating environment specified in this Directions For Use (DFU) including general wards, critical and intensive care, neonatal, operating rooms and accident and emergency rooms.

This pump is suitable for use by appropriately trained clinicians or nurses. The pump is suitable to deliver fluids and medications via intravenous and epidural routes. Supporting fluid therapy, blood transfusions and parenteral feeding.

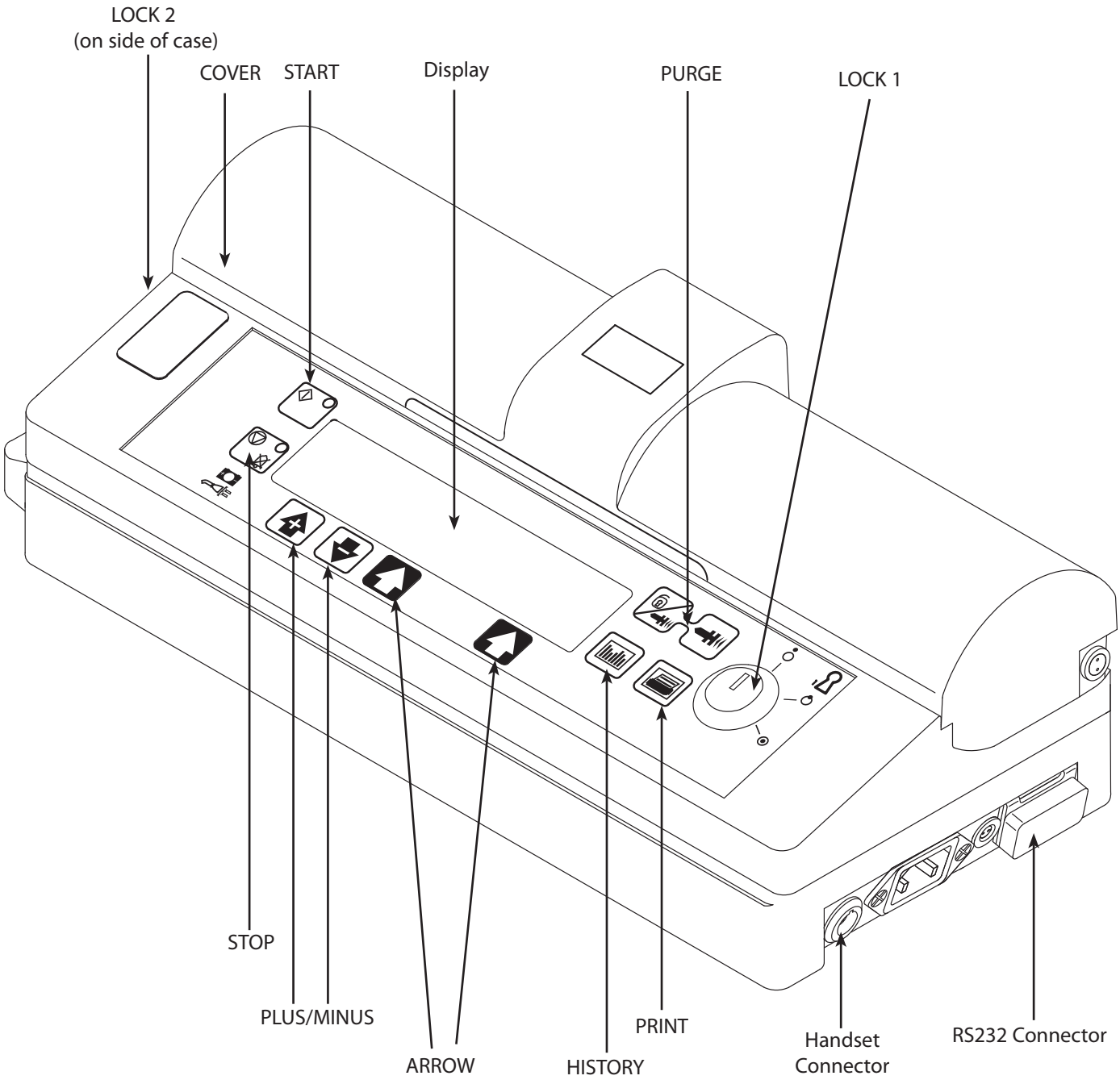
The pump is compatible with a wide range of standard, single-use, disposable Luer-lock syringes. It accepts syringe sizes from 20 ml to 100 ml. See the 'Compatible Syringes' section for a full list of compatible syringes.

- User configured PCA protocols.
- Comprehensive history.
- Large graphics format display.
- Two key positions providing separation of nursing and programming procedures.
- 10 pre-set hospital PCA protocols.
- Unique electronic hand set with status indicator.
- Communications and nurse call interfaces.

About This Manual

The user must be thoroughly familiar with the IVAC® PCAM® Syringe Pump described in this manual prior to use.

All illustrations used in this manual show typical settings and values which may be used in setting up the functions of the pump. These settings and values are for illustrative use only. Where stated, a minimum infusion rate refers to a nominal rate of 1.0ml/h, and an intermediate infusion rate refers to a nominal rate of 5.0ml/h. The complete range of infusion rates, settings and values are shown in the Specifications section.


LOCK 2
(on side of case)
COVER
START
Display
PURGE
LOCK 1
STOP
PLUS/MINUS
ARROW
HISTORY
PRINT
Handset
Connector
RS232 Connector

Controls & Indicators

Controls:

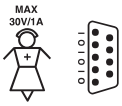
Symbol	Description
	**START** button - Press to start the infusion. The green LED will flash during infusion.
	**STOP** button - Press to put the infusion on hold. The amber LED will be lit while on hold.
	**PURGE** button - Press and hold both buttons to purge the extension set during set up. See 'Basic Features' for further information.
	**HISTORY** button - Press to display PCA demands and drug infused history graphs, 24 hour review and event log.
	**PRINT** button - Press to print patient history. Note: A suitable printer must be connected to the pump.
	**PLUS/MINUS** buttons - Use to move cursor and to increase or decrease values shown on main display.
	**ARROW** buttons - Use as softkeys in conjunction with the prompts shown on the display.
 OFF  SET  RUN	**LOCK 1 -** Insert key into **LOCK 1** keyswitch and turn key to switch between **OFF**, **SET** and **RUN** positions. **OFF** - Turns the power off. **SET** - Use to select or modify protocols and to access configuration and test routines. **RUN** - Use to start the infusion. Note: Switching from **RUN** mode to **SET** mode without first pressing the **STOP** button automatically stops the infusion.
	**LOCK 2 -** Insert key into **LOCK 2** and turn key clockwise to open the syringe cover. **(This key lock is located on the left side of the pump)**

Indicators:

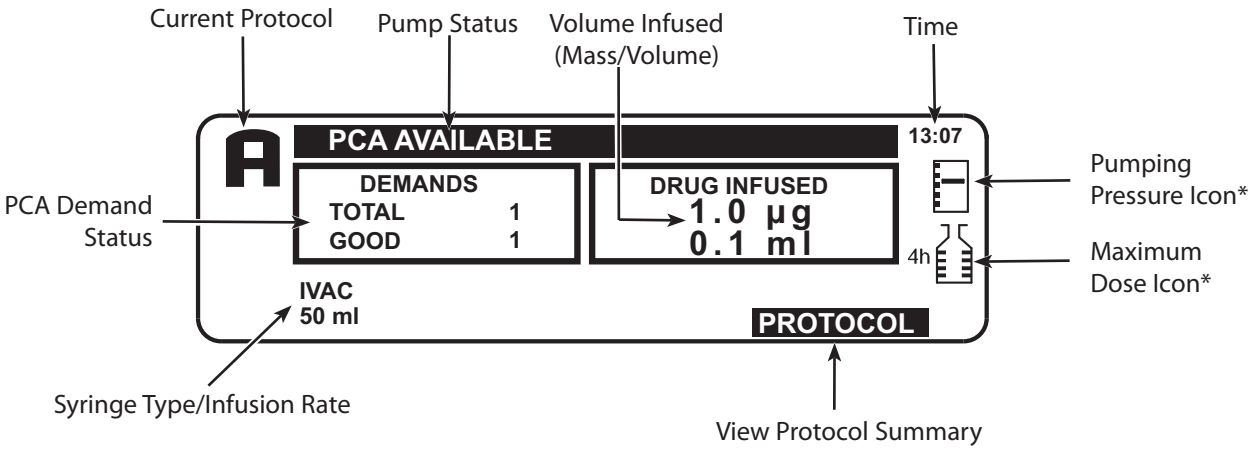
Symbol	Description
	**BATTERY** indicator - When illuminated the pump is running on the internal battery. When flashing the battery power is low with less than 30 minutes of use remaining.
	**AC POWER** indicator - When illuminated the pump is connected to an AC power supply and the battery is being charged.

Symbol Definitions

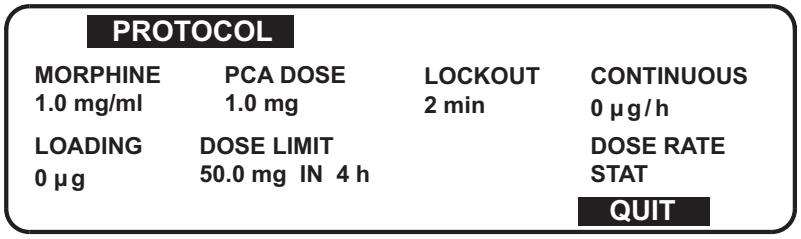
Labelling Symbols:

Symbol	Description
	Attention (Consult accompanying documents)
	Potential Equalisation (PE) Connector
	RS232/Nurse call Connector (Optional)
	Class II Equipment
	Type CF applied part (Degree of protection against electrical shock)
IPX4	Protected against splashing fluid (degree of protection against fluid ingress)
	Alternating Current
CE 0086	Device complies with the requirements of the EC Directive 93/42/EEC. Registered with the CE Mark.
	Date of Manufacture
	Manufacturer
	Not for Municipal Waste
	Important information

Main Display



Protocol Summary Screen



* These icons are not displayed when disabled.

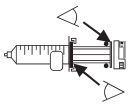
Screen Icons:

Symbol	Description
	**PUMPING PRESSURE** icon - When enabled, this icon is shown on the Display. It provides a visual indicator of current pumping pressure and pressure level at which the alarm will operate.
	**MAXIMUM DOSE** icon - When enabled, this icon is shown on the Display. It provides a visual indication of the amount of drug administered during the limit period (as shown to the left of the icon). If the dose limit reaches the alarm level, the bottle icon will appear full, the pump will stop infusing and the message **Max Dose Limit** is displayed and the icon will flash until the dosing is less than the maximum dose limit. Clinician over-ride is always available.
	**BACK** icon - Indicates the softkey to press to go back to previous screen.

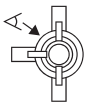
Operating Precautions

Disposable Syringes and Extension Sets

- This pump has been calibrated for use with single-use disposable syringes. To ensure correct and accurate operation, only use 3 piece Luer-Lock versions of the syringe make specified on the pump or described in this manual. Use of non-specified syringes or extension sets may impair the operation of the pump and the accuracy of the infusion.

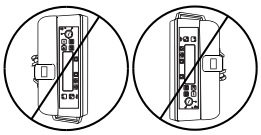


- Uncontrolled flow or syphoning may result if the syringe is located incorrectly in the pump, or if it is removed from the pump before the extension set is properly isolated from the patient. Isolation may include closing a tap in the extension set or activating a flow stop clamp.



- When combining several apparatus and/or instruments with extension sets and other tubing, for example via a 3-way tap, the performance of the pump may be impacted and should be monitored closely.

Mounting the Pump



- Do not mount the pump in a vertical position with the syringe pointing upwards as this could lead to an infusion of air which may be in the syringe. To protect against the introduction of air the user should regularly monitor the progress of the infusion, syringe, extension set and patient connections and follow the priming procedure specified herein.

Operating Environment

- When using any infusion pump in conjunction with other pumps or devices requiring vascular access, extra care is advised. Adverse delivery of medication or fluids can be caused by the substantial variation in pressures created within the local vascular system by such pumps. Typical examples of those pumps are used during dialysis, bypass or cardiac assist applications.

- This pump is suitable for use in Hospital and clinical environments other than domestic establishments and those directly connected to the public single phase AC mains power supply network that supplies buildings used for domestic purposes. However, it may be used in domestic establishments under the supervision of Medical professionals with additional necessary appropriate measures. (Consult Technical Service Manual, appropriately trained technical personnel or Cardinal Health for further information).

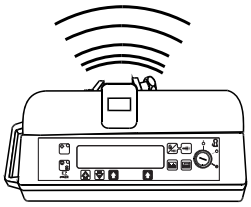
- This pump is not intended to be used in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

Operating Pressure

- This is a positive pressure pump designed to achieve very accurate fluid administration by automatically compensating for resistance encountered in the infusion system.

- The pumping pressure alarm system is not designed to provide protection against, or detection of, IV complications which can occur.

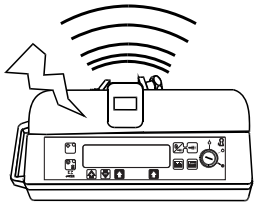
Alarm Conditions



- Several alarm conditions detected by this pump will stop the infusion and generate visual and audible alarms. Users must perform regular checks to ensure that the infusion is progressing correctly and no alarms are operating.

Electromagnetic Compatibility & Interference

- This pump is protected against the effects of external interference, including high energy radio frequency emissions, magnetic fields and electrostatic discharge (for example, as generated by electrosurgical and cauterising equipment, large motors, portable radios, cellular telephones etc.) and is designed to remain safe when unreasonable levels of interference are encountered.
- **Therapeutic Radiation Equipment:** Do not use the pump in the vicinity of any Therapeutic Radiation Equipment. Levels of radiation generated by the radiation therapy equipment such as Linear Accelerator, may severely affect functioning of the pump. Please consult manufacturer's recommendations for safe distance and other precautionary requirements. For further information, please contact your local Cardinal Health representative.
- **Magnetic Resonance Imaging (MRI):** The pump contains ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the pump is not considered an MRI compatible pump as such. If use of the pump within an MRI environment is unavoidable, then Cardinal Health highly recommends securing the pump at a safe distance from the magnetic field outside the identified 'Controlled Access Area' in order to evade any magnetic interference to the pump; or MRI image distortion. This safe distance should be established in accordance with the manufacturers' recommendations regarding electromagnetic interference (EMI). For further information, please refer to the product technical service manual (TSM). Alternatively, contact your local Cardinal Health representative for further guidance.
- **Accessories:** Do not use any non-recommended accessory with the pump. The pump is tested and compliant with the relevant EMC claims only with the recommended accessories. Use of any accessory, transducer or cable other than those specified by Cardinal Health may result in increased emissions or decreased pump immunity.
- This pump is a CISPR 11 Group 1 Class A device and uses RF energy only for its internal function in the normal product offering. Therefore, its RF emissions are very low and are not likely to cause any interference with the nearby electronic equipment. However, this pump emits a certain level of electromagnetic radiation which is within the levels specified by IEC/EN60601-1-2 and IEC/EN60601-2-24. If the pump interacts with other equipment, measures should be taken to minimise the effects, for instance by repositioning or relocation.



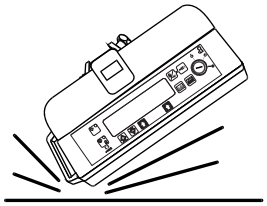
- In some circumstances the pump may be affected by an electrostatic discharge through air at levels close to or above 15kV; or by radio frequency radiation close to or above 10V/m. If the pump is affected by this external interference the pump will remain in a safe mode; the pump will duly stop the infusion and alert the user by generating a combination of visual and audible alarms. Should any encountered alarm condition persist even after user intervention, it is recommended to replace that particular pump and quarantine the pump for the attention of appropriately trained technical personnel. (Consult Technical Service Manual for further information).

Hazards

- An explosion hazard exists if the pump is used in the presence of flammable anaesthetics. Exercise care to locate the pump away from any such hazardous sources.

- Dangerous Voltage: An electrical shock hazard exists if the pump's casing is opened or removed. Refer all servicing to qualified service personnel.

- Do not open the RS232 protective covering when not in use. Electrostatic discharge (ESD) precautions are required when connecting RS232. Touching the pins of the connectors may result in ESD protection failure. It is recommended that all actions must be taken by appropriately trained personnel.



- If this pump is dropped, subjected to excessive moisture, fluid spillage, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by a qualified service engineer. When transporting or storing the pump, use original packaging where possible, and adhere to temperature, humidity and pressure ranges stated in the Specifications section and on the outer packaging.

Latex Content

- The pump and handset do not contain any Latex.

Getting Started

Initial Set-up

Before operating the pump read this Directions For Use manual carefully.

1. Check that the pump is complete, undamaged and that the voltage rating specified on the label is compatible with your AC power supply.
2. Items supplied are:
   - ***IVAC® PCAM® Syringe Pump***
   - ***User Support CD (Directions For Use)***
   - ***AC Power Cable (as requested)***
   - ***Protective Packaging***
3. Connect the pump to the AC power supply for 24 hours to ensure that the internal battery is fully charged (verify that the is lit).

The pump will automatically operate from its internal battery if the pump is switched on without being connected to the AC power supply. Prior to use on battery power, verify the pump continues to function on battery power once disconnected from the AC power supply.

Should the pump fail to perform correctly, replace in its original protective packaging, where possible and contact a qualified service engineer for investigation.

Do not mount the pump with the AC power inlet or the syringe pointing upwards. This could affect the electrical safety in the event of a fluid spill or lead to the infusion of air which may be in the syringe.

Pole Clamp Installation

The pole clamp is supplied fitted to the rear of the pump and will provide secure fixing to standard I.V. poles of a diameter of up to 40mm.

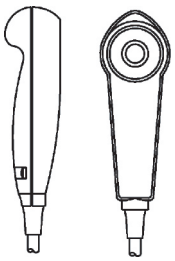
The pole clamp can also be fitted in a choice of 4 fixing positions allowing the pump to be mounted to vertical and horizontal poles, equipment rails and hospital furniture in a variety of convenient operating orientations.

The pole clamp may be adjusted for use with horizontal fittings by using the existing fixings screws with the alternative fixing holes in the pole clamp.

The pole clamp may also be secured to the base of the pump in a choice of four positions.

Patient Hand Set

The patient hand set supplied with the pump is designed to be ambidextrous and suitable for both adult and paediatric use. The hand set provides an indicator light which clearly shows when the pump is available and can be configured to flash when a PCA dose is being delivered.

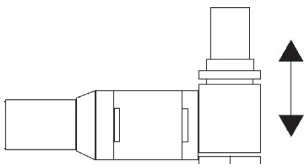


The indicator on the patient hand set will reflect the configuration of the pump and will provide feed-back on all, or just good demands, and the indicator light can be disabled should the clinical situation require.

Where appropriate the hand set can be configured so that the patient will not need to refer to the instrument to assess if PCA is being delivered, or is available.

The hand set is provided with a clip for attaching it to bedding or clothing.

The pump concept is that the patient can be instructed in the use of the hand set as it will carry all the information required by the patient using PCA. This design simplifies patient instruction and encourages a smooth transfer to alternative devices used to treat long term chronic pain, should this be indicated.



A latching (but non locking) connector makes the hand set easy to fit. To remove, hold the body of the connector and pull away from the pump.

An alarm warning will operate if the hand set is disconnected from the pump while it is in operation or the hand set is connected to the unit with the PCA button depressed. In addition, the pump can be operated in continuous or clinician over-ride modes without the hand set connected, should this be required.

Loading a Syringe

Only use a syringe of the type stated on the pump or in this manual. Using an incorrect syringe could adversely affect the accuracy of the infusion and the performance of the pump.

When initially loading the syringe, allow for the volume of fluid contained in the extension set and retained in the syringe at the end of infusion as this "dead-space" will not be infused.

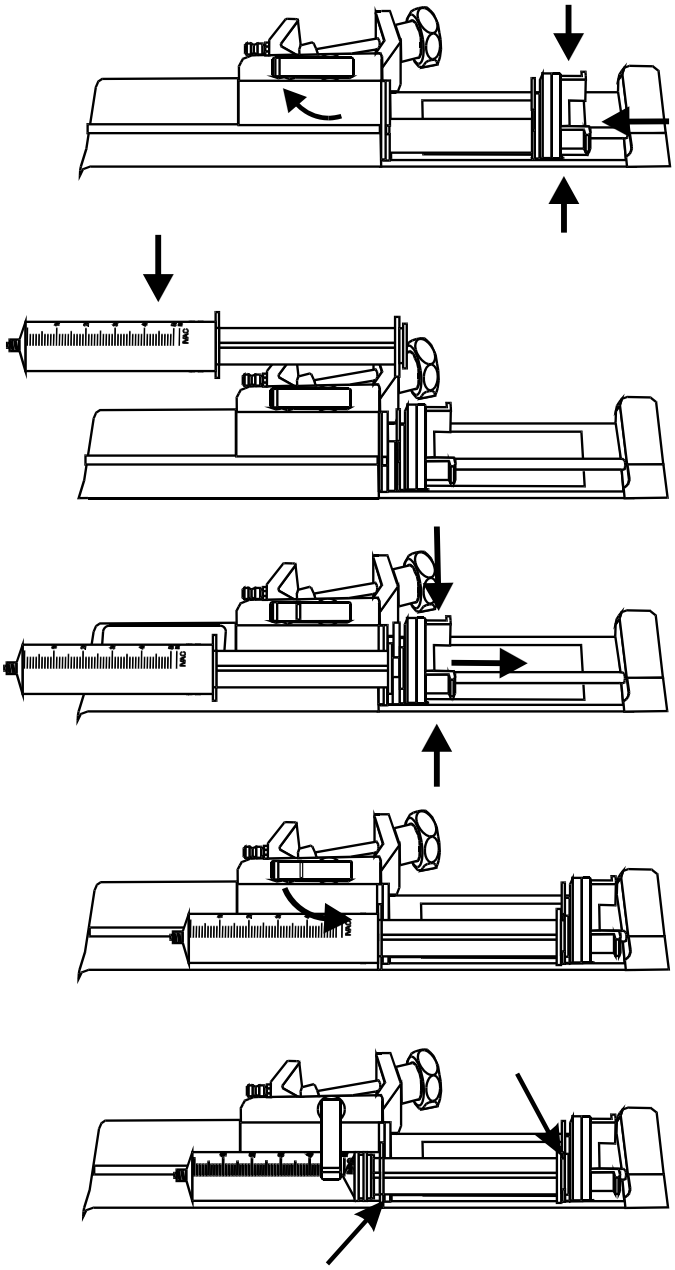
Place the pump on a stable horizontal surface or secure as described above.

Prepare, load and prime the single-use disposable syringe and extension set using standard aseptic techniques.

1. Squeeze the finger grips on the plunger holder and slide the mechanism to the left. Lift the syringe clamp and rotate clockwise.
2. Insert the syringe into the slots on the plunger holder.
3. Squeeze the finger grips on the plunger holder and slide the mechanism to the right until the syringe finger flanges locates in the V slot.

Gently advance the syringe until the finger flanges touch the front of the V slot closest to the syringe clamp. This is important to prevent delay at the start of the infusion.

4. Rotate the syringe clamp anticlockwise until it locks onto the syringe barrel to secure the syringe.
5. Check that the syringe plunger and finger flanges are correctly located in their slots.



Changing a Syringe during an infusion

When changing the syringe LOCK 1 should remain in the RUN position except when a change is required to the protocol.

1. Press the button to halt the infusion and place the pump on hold.
2. Open the cover using **LOCK 2**.
3. Close the extension line to the patient.
4. Change the syringe, fitting the new syringe as per instructions above.
5. Follow steps 7 to 10 of 'Starting the Pump' section on the next page.

Starting the Pump

1. AC POWER - Connect pump to AC power supply using the AC power cable. Note: the pump will operate on an internal battery when not connected to an AC power source for a limited time.

> ***Prior to beginning an infusion, disconnect the pump from the AC power supply, confirm the pump continues to function on battery power. Then reconnect the pump to the AC power source.***

2. SET - Insert key into **LOCK 1**. Turn to **SET** position.

3. **NEW PATIENT?** - Answering **NO** will retain all previous patient history, except for the PCA lockout time remaining which will be reset to PCA AVAILABLE. **YES** will automatically reset the patient history to zero. Check time and date is correct and answer **YES** or **NO**.

4. **SELECT/ MODIFY PROTOCOL** - Carefully check the protocol displayed. If required, press **MODIFY PROTOCOL** to adjust the current protocol, or, **NEXT PROTOCOL** to select an alternative pre-set protocol.

5. RUN - Turn **LOCK 1** to the **RUN** position and remove the key from pump.

6. CONFIRM PROTOCOL - Carefully check that protocol is correct. Press **OK**.

7. CONFIRM SYRINGE - Check that the syringe type and size being used matches display. If required, the make of syringe can be changed by pressing the **CHANGE TYPE** softkey. Press **OK**.

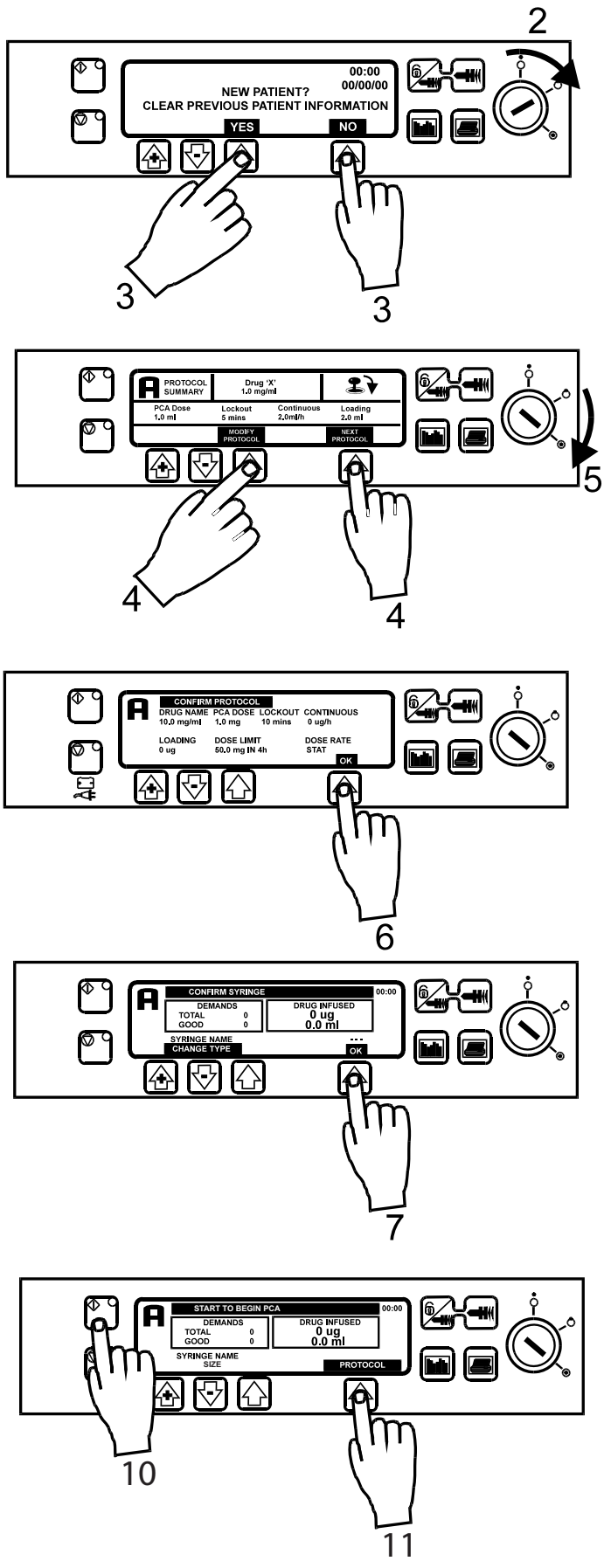
8. PURGE (if required) - The **PURGE** buttons can only be used when the cover is open and **LOCK 1** is in the **RUN** position. When the purge operation is complete close the cover.

9. CONNECT PATIENT - Connect the PCA extension set to the patient access device. Recheck the protocol.

10. START - Press the ⏲ button to commence pump operation. Either **PCA AVAILABLE** or **CONTINUOUS INFUSION** will be displayed with the rate, demand and drug totals. If selected, a loading dose will be delivered.

11. PROTOCOL - Press **PROTOCOL** softkey at any time to display the protocol summary. To return to the main screen press **QUIT**.

> ***The pump will automatically operate from its internal battery if the pump is switched on without being connected to the AC power supply.***
> ***Each time the pump is switched ON, check that the alarm beeps twice and that all the segments of the display, the green and amber lights are illuminated during the self test routine.***
> ***LOCK 1 should not be turned from OFF to SET whilst the syringe extension set is connected to the patient.***

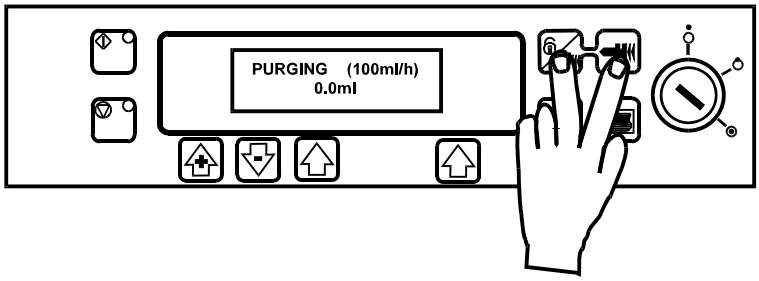


Basic Features

Purge

The button allows the delivery of a limited volume of fluid in order to purge the extension set prior to being connected to a patient.

1. **PURGE** can only be operated with the cover opened and **LOCK 1** in the **RUN** position.
2. Press the buttons together until fluid flows and priming of the syringe extension set is complete. The audible alarm will operate during use of the buttons and the volume used during priming will be shown in the volume infused display.

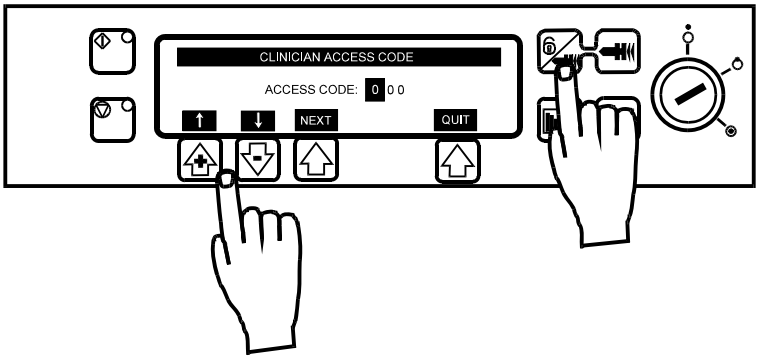


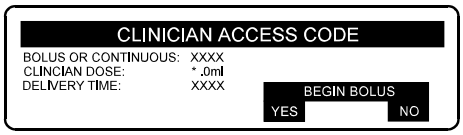
The PURGE feature is not activated when the cover is closed. Ensure that the extension set is disconnected from the patient before purging the line. No alarms are disabled during the operation of the PURGE feature. During PURGE the pressure limit alarms are temporarily increased to their maximum level.

Clinician Over-ride

The clinician over-ride feature can be used in RUN mode to administer an additional bolus dose or continuous background infusion of a limited dose and duration, for example during the PCA lock out period. The clinician over-ride is a special feature which can be configured according to the specific clinical situation. Clinician over-ride can also be used in SET mode to allow modification of the pre-set PCA Protocol when this option has been disabled for normal use.

1. Turn **LOCK 1** to **RUN** position and ensure green light is illuminated on the button.
2. Press and hold down the button for 2 seconds.
3. Use buttons and **NEXT** softkey to enter three figure pre-programmed clinician access code. See technical service manual.
4. Select **BOLUS** or **CONTINUOUS**.
5. Use buttons to select the dose delivered, when the correct value has been entered press **OK**.
6. Use buttons to select period over which the dose is to be delivered. Press **OK** when correct time has been entered.
7. **BEGIN BOLUS? YES** - Clinician bolus / continuous infusion will be delivered to the patient. **NO** - Quit set up and return to normal operation.





The delivery of the clinician over-ride continuous infusion will automatically halt while a Patient or Clinician over-ride bolus is being administrated. To cancel clinician over-ride during delivery, press button and press the YES softkey. During BOLUS the pressure limit alarms are temporarily increased to their maximum level.

Basic Features (Continued)

Patient History

Each time the pump is switched ON it will ask if this is a new patient. Pressing **YES** will provide opportunity to re-set patient history. Pressing **NO** continues with the current protocol and retains all protocol records, event history, graphs etc. However, any remaining PCA lockout time will be cleared and a PCA demand will be immediately available.

The pump will retain the events in a rolling memory. Following selection of a new patient, it remains possible in technician mode to access previous patient(s) history still held in memory.

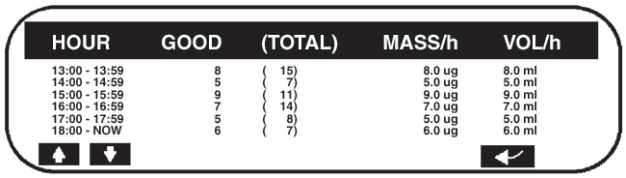
Patient history can be accessed at any time by pressing the button. The pump provides a clear rolling 24 hour graphical representation of the PCA demand pattern and the drug administered to the patient. The graphs are updated when the history button is pressed and give values for each completed hour and the current hour. The cumulative counters on the Drug Infused history screen update in real-time.

24 Hour Review

An hour by hour record of the last 24 hours, showing good and total PCA demands along with the total dose and volume per hour.

This information provides the accurate demand pattern and drug infused values from which the other graphs are derived.

1. To access the 24 Hour Review press the button once.
2. To return to the previous screen press the **BACK** softkey.
3. To scroll through to the next History screen press the button.

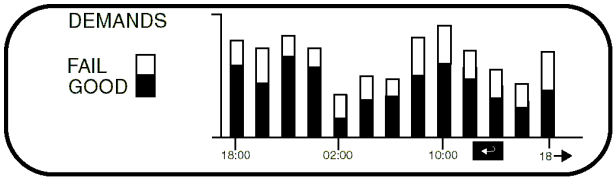


PCA Demands

Provides a record of the last 24 hours good and failed PCA demands. The good demands are indicated by the shaded section of the graph and the failed demands by the clear section. The latest hour is shown at the right side of the display.

This graph provides a clear picture of good and bad PCA demands and pattern of the patients usage. Used in conjunction with the PCA Demands graph, this display helps to indicate if the PCA protocol needs modification and when to end treatment.

1. To access the PCA demand graph press the button twice.
2. To exit the screen press the **BACK** softkey.
3. To scroll through to the next History screen press the button.

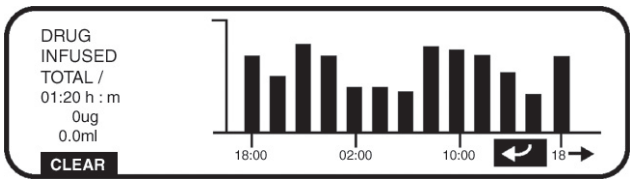


Drug Infused

Record of the total amount of drug administered to the patient over the last 24 hours. The latest hour is shown at the right side of the display. This graph provides a clear picture of the actual drug administered, including loading dose, continuous background infusions, clinician over-rides and protocol changes. The left side of the display shows cumulative dose and time counters with the time, mass and volume infused since the patient session started or since the counters were last reset. To reset counters press **CLEAR** and then **CONFIRM**.

Used in conjunction with the PCA Demands graph, this display helps to indicate relative pattern of the demand pattern and the actual drug administered.

1. To access the Drug Infused graph press the button three times.
2. To return to the previous screen press the **BACK** softkey.
3. To scroll through to the next History screen press the button.

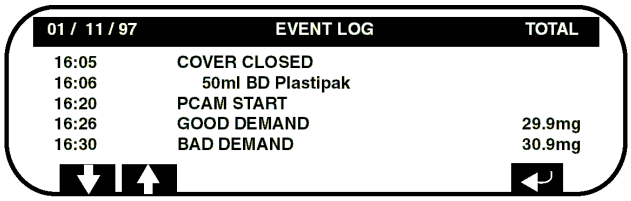


Event Log

Record of events since "**NEW PATIENT**" selected. Including, protocol selection and changes, patient demands etc. The event log will also record all alarms.

All events are recorded against date, clock and total drug infused.

1. To access the Event Log press the button four times.
2. To return to the previous screen press the **BACK** softkey.
3. To return to the Protocol Summary press the button again.



Printing

A printer fitted with a serial interface (or cable with parallel to serial converter) can be connected to the pump, either during normal PCA operation or following use. Printing patient history provides a permanent record and can be used for analysis away from the bedside.

All patient history, including protocols and the 24 hour demand pattern and drug dose administered graphs are available for printing.

When connected to the printer, the pump can also be configured to provide line by line continuous printing of all events, patient demands etc. as they occur at the bedside. See General Options.

Print	Connect Printer then...	Information printed
Protocol Summary	• Turn **LOCK 1** to **SET** position • Press button	All protocol information will be printed with patient header.
Patient History	• Press button	All protocol information, demand and drug totals, 24 hour graphs and records will be printed with patient header.
Event Log	• Press button until event log is displayed. • Use buttons to position display at start point for events to be printed. • Press button	All events will be printed from information on screen forward with time, date and patient header.
Event Log at New Patient	• Press button	All events will be printed from the patient event log.

Continuous Mode

Enable Continuous printing by selecting **YES** in General Options.

1. Connect printer.
2. All events will be printed as they occur.

Teach Learn Mode

By programming the configuration of one pump in the conventional way from the front panel buttons other pumps can have the configuration copied over using the "teach" and "learn" modes.

When set to "learn" mode the pump will accept information sets from a pre-configured pump set to "teach" mode.

When set to "teach" mode the pump sends out via the communications interface a sequence of all the information sets required to configure another pump. To fully configure a pump it is necessary to send 22 complete information sets as described in the protocols and the full cycle takes about 22 seconds.

The two pumps must be connected together using an RS232 Demonstration Cable. Both pumps must be of the same version software and revision and set to a common pump comms identification number (see General Options). The configured pump is set to "teach" mode and the pump to be configured is set to" learn" mode using the access codes listed in the Technical Service Manual. The pump in "learn" mode will display **PASS** or **FAIL** for each information set being received from the "teach" mode device.

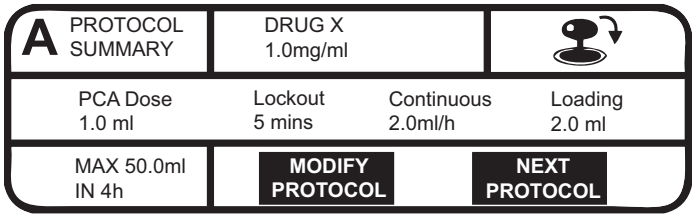
The pumps must run through at least one complete sequence of the information sets and then switch off first the "learn" pump and then the "teach" pump. ***After using this method it is the user's responsibility to check that the configuration has been copied over correctly.***

Pre-Set PCA Protocols

Operation of the pump is greatly simplified by the use of PRE-SET PCA protocols. When **LOCK 1** is turned to the **SET** position the pump will automatically display pre-set **PROTOCOL A** if **NEW PATIENT** has been selected or display the previous protocol in use if **NEW PATIENT** has not been selected.

With **LOCK 1** in the **SET** position, it is possible for the user to modify the pre-set protocol using the **MODIFY PROTOCOL** button and select another pre-set protocol using the **NEXT PROTOCOL** button.

To modify a Pre-Set Protocol



1. Press **MODIFY PROTOCOL** indicated on the screen.
2. The protocol summary will be displayed. Use ⌂ buttons to highlight a field, press **ALTER** to enter that field and ⌂ ⌂ buttons to select desired values.
3. When field is correct press **CONFIRM** or **CANCEL**.
4. Display will show:

A

Protocol		
Drug name	**Drug 'X'**	
Drug conc.	**1.0mg/ml**	
PCA Dose	**1.0mg**	**(1.0ml)**
Lockout period	**5 mins**	
Occlusion level	**4**	
Continuous	**0µg/h**	**(0.0ml/h)**
Loading dose	**0µg**	**(0.0ml)**
Max. limit	**50mg**	**(50.0ml)**
Limit duration	**4 hours**	
PCA delivery	**STAT**	

5. Press **OK** to return to display.

Notes:

A modified protocol has no pre-set letter.

*To utilise this function, "**MODIFY PROTOCOL"** must be enabled in **GENERAL OPTIONS.***

To change to another Pre-Set Protocol

Press **NEXT PROTOCOL** to display the step through the pre-set protocol.

Pre-set protocols are identified as A to J. When the desired protocol has been selected it can be used by turning **LOCK 1** to the **RUN** position, or, can be modified using the **MODIFY PROTOCOL**.

To confirm a Protocol

Whenever a new protocol is selected, modified or **LOCK 1** is turned to the **SET** position, the **CONFIRM PROTOCOL** display will appear. Pressing **OK** automatically records the protocol and any changes in the **EVENT LOG** history.

If the calculated rate goes to more than one decimal place, the pump displays the rate to one decimal place only; however the pump will infuse at a rate equivalent to two decimal places. The displayed rate will be rounded down to prevent the user believing an over infusion is taking place.

For Example:

If 30µg/h was required using a drug preparation of 44µg/ml, this would equate to a rate of 0.681818ml/h.

The pump will round the calculation to two decimal places, giving an actual infusion rate of 0.68ml/h, whilst the screen which can only display to one decimal place will show as 0.6ml/h

Alarms

Alarms are indicated by a combination of an audible alarm, flashing amber STOP light and a descriptive message in the display.

1. First press the **MUTE** softkey to silence the alarm for a maximum of 2 minutes, then check the display for an alarm message. Press to cancel the alarm message.
2. If the infusion has stopped, rectify the cause of the alarm then press the button to resume the infusion.

Message	*Cause and Troubleshooting Guide*
DRIVE DISENGAGED	PUMP DRIVE DISENGAGED The drive system has been disengaged during operation. Use **LOCK 2** to unlock and open the cover. Check the finger grips and the position of the syringe.
COVER OPENED	COVER OPENED DURING OPERATION The cover has been opened during operation. Check cover and **LOCK 2**.
LINE OCCLUSION	EXCESSIVE PUMPING PRESSURE Pumping pressure has reached the alarm limit. Use **LOCK 2** to unlock and open the cover, squeeze finger grips on the plunger holder to release the drive mechanism and relieve any excessive pressure in the syringe and patient line. Identify and remove the cause of the blockage in the drive, syringe, or administration system before restarting the infusion.
SYRINGE ERROR	SYRINGE SIZE ERROR / FITTED INCORRECTLY Incorrect size of syringe has been fitted, the syringe clamp has not been positioned correctly on the syringe or has been disturbed during operation or plunger is not fitted in plunger slot. Use **LOCK 2** to unlock and open the cover, check syringe size, position of syringe clamp, syringe and plunger.
CHECK HANDSET	PATIENT HAND SET FAILURE Patient hand set has become faulty or disconnected during operation. Check operation and connection of the hand set to the pump. Press to continue if operation without the hand set is required.
BATTERY LOW	BATTERY CHARGE LOW WARNING Battery charge low with 30 minutes operation remaining. Battery indicator will flash and after 30 minutes a continuous audible alarm will indicate that the battery is exhausted. Reconnect to AC power supply to continue operation and charge internal battery.
BATTERY EXHAUSTED	BATTERY EXHAUSTED Internal battery exhausted. To silence the alarm switch **LOCK 1** to the **OFF** position and reconnect pump to AC power supply. Restart operation on AC power whilst charging the internal battery. Switch to the **RUN** position.
SYRINGE NEAR EMPTY	NEAR END OF SYRINGE WARNING Syringe almost empty with about 6% of its volume remaining. Press to silence alarm and continue operation. Display will flash **SYRINGE NEAR EMPTY**. The alarm screen will also flash **USE LOCK 2 TO OPEN COVER.**
SYRINGE EMPTY	SYRINGE EMPTY - END OF INFUSION The pump has reached the end of the infusion. About 1% of the syringe volume will remain in the syringe helping to prevent the infusion of air bubbles into the PCA set. The alarm screen will flash **USE LOCK 2 TO OPEN COVER.**
AC POWER FAIL	AC POWER SUPPLY DISCONNECTED WARNING AC Power has been disconnected and the pump is operating on battery power. Reconnect AC power supply or press to silence the alarm and continue battery operation. The display will light up **ON BATTERY**. The alarm will automatically cancel if the AC power supply is reconnected.
MALFUNCTION	INTERNAL MALFUNCTION The alarm system has detected an internal malfunction. Note the malfunction code. Remove pump from service for examination by a qualified service engineer.
MAX DOSE EXCEEDED	MAX DOSE LIMIT The maximum dose over time limit has been exceeded. Infusion is stopped when the alarm occurs. Press to cancel the alarm. The max dose icon will flash until dosing is less than the maximum dose limit. Note that this alarm can be disabled under General Options.
3 BEEPS *(Alarm without screen prompt)*	NURSE ATTENTION WARNING Pump left switched **ON** for more than 2 minutes without starting operation. Press or any of the control buttons to silence the alarm for a further 2 minutes. To cancel this alarm for 15 minutes, press and hold the button until 3 rapid, consecutive beeps are heard.

Configured Options

This menu comprises a list of options which are configurable by the user.

1. Whilst holding down the button turn the pump **ON**.
2. The main display will show **000**. Enter the access code for Configured Options using the buttons, pressing **NEXT** to move through the digits. A full list of access codes can be found in the Technical Service Manual.
3. When the complete code shows on screen, press **ENTER**. The Configured Options menu will be displayed.

General Options

1. Select **GENERAL OPTIONS** from the menu using the buttons and press **ENTER**.
2. Select the option you wish to enable/disable or adjust and press **MODIFY**.
3. When all the desired modifications have been carried out press **QUIT**.
4. Either select the next configuration option from the menu or turn the pump **OFF**, returning it to operation as required.

Option	Description
1. ICONS on display	YES - displays Pumping Pressure and Maximum Dose ICONS. NO - ICONS disabled.
2. Protocols in use	PCA pre-set protocols to be available. Select number from 1 to 10.
3. Modify protocol	YES - allows protocols to be modified in SET mode. NO - removes modify protocol option in SET mode.
4. Handset mode	MODE A B C BEEP GOOD ALL ALL HAND SET LIGHT: PCAM® STOPPED OFF OFF OFF PCA AVAILABLE ON ON ON PCA DELIVERING FLASH ON FLASH PCA LOCK-OUT OFF ON ON
5. Delayed call-back	YES - call-back alarm can be delayed from 10 mins up to 90 mins. NO - call-back will be cancelled for up to 2 mins or extended to 15 mins. To extend call-back alarms, press and hold the button for 4 seconds.
6. Display Sleep	YES - display goes blank after 2 minutes. NO - display stays on during operation.
7. Chirp low alarms	YES - "chirp" alarm during use on battery/near end. NO - no "chirp" alarm.
8. Continuous infusions	YES - Continuous infusions option in protocols. NO - Continuous infusions are not available.
9. Loading doses	YES - Loading dose option appears in protocols. To activate this option "NEW PATIENT" is confirmed. The protocol also includes the loading dose. Start the PCA. NO - Loading doses are not available.
10. Max. dose limits	YES - Dose limit option appears in protocols. NO - Dose limits are not available.
11. Variable dose rates	YES - Allows the dose rate to be varied, when modifying the protocol. Dose rate can be either STAT rate (100ml/h max.) or the dose can be delivered over a period of time from 1 to 60 minutes. NO - Each dose will be delivered at the STAT rate and there is no option to change when modifying the protocol.
12. Comms identity number	Use buttons to set pump identity (between 000 and 127) for use with remote communications.
13. Comms enabled	YES - RS232 Communications enabled. NO - RS232 Communications disabled.
14. Nurse call	YES - Nurse call connector enabled. NO - Nurse call connector disabled.
15. Nurse call inverted	YES - Nurse call inverted enabled. NO - Nurse call inverted disabled

Configured Options (Continued)

General Options (continued)

Option	Description
16. Continuous Print	YES - Allows printing of events as they happen. NO - Continuous printing disabled.
17. Default Syringe	Use buttons to select the default syringe brand.
18. Lock syringe type	YES - Syringe type locked to default syringe. NO - Syringe type not locked to default syringe.
19. Quiet mode	YES - Quiet mode enabled. NO - Quiet mode disabled.
20. Generic Drug Enabled	YES - Allows Protocols to be set up to use a Generic Drug, which is preset to maximum safety limits. NO - Disallows use of Generic Drug.
21. Max Dose Limit Alarm	YES - Alarm is generated when max dose limit is reached. NO - Alarm is not generated when max dose limit is reached.
22. Mix Mass & Vol Modes	YES - Allow a mix of mass and volume dose mode for drugs and protocols. NO - All drugs and protocols use mass dose mode.

Clock Set

1. Select **CLOCK SET** from the Configured Options menu and press **ENTER**.
2. Use the buttons to adjust the date and time displayed, pressing **NEXT** to access the next field.
3. When the correct time and date are displayed press **OK** to return to the Configured Options menu.

The internal clock is the reference against which the pump stores patient history and events. Changing the clock will automatically reset the dates against which all new patient history is stored in the pump. After changing the clock, the pump will force a YES response the next time the NEW PATIENT screen appears. This will clear the patient history. Therefore, patient history should always be recorded and, if required, printed prior to changing the clock.

Pre-Set Protocol Set-Up

1. Select **PROTOCOL DEFAULT SET-UP** from the Configured Options menu and press **ENTER**.
2. Press **MODIFY PROTOCOL** to display current protocol summary. Use the buttons to highlight a field, press **ALTER** to access the field and the buttons to select required values.
3. When the field is correct press **CONFIRM**. Press **OK** to return to the protocol summary.

One of the ten drugs programmed in the Drug Names and Safety Limits are selectable for each protocol. Additionally a default drug with limits set to extremes may be chosen if Generic Drug is enabled in General Options. Default drugs are named "MASS DRUG" and "VOL DRUG". The names indicate the underlying dose mode.

Hospital Name

This option allows the user to programme in the name of the hospital, ward or department. This will appear during the power-up display sequence and the 'Display Sleep' screen (if enabled in General Options).

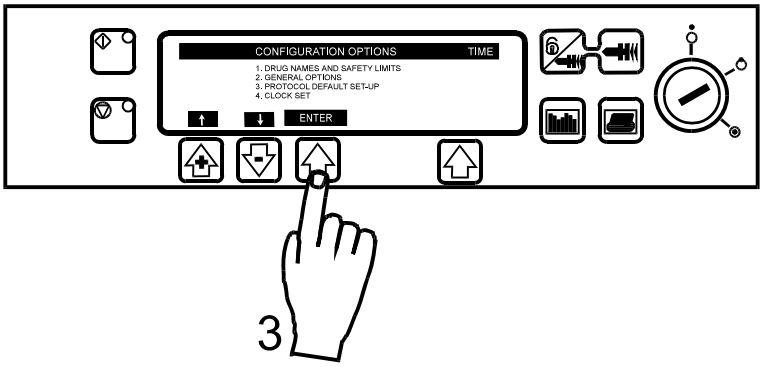
1. Whilst holding down the button turn the pump **ON**.
2. The main display will show **000**. Enter the access code for Hospital Name using the buttons, pressing **NEXT** to move through the digits. A full list of access codes can be found in the Technical Service Manual.
3. When the complete code shows on screen, press **ENTER**. The Hospital Name Option will be displayed.
4. Use the buttons to adjust the character displayed, pressing **NEXT** to access the next position.
5. When the correct name is displayed turn **LOCK 1** to the the **OFF** position.

Drug Names and Safety Limits

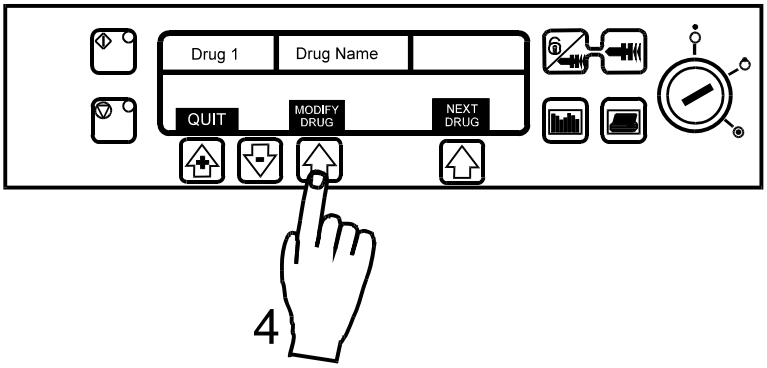
If enabled in General Options, a drug can be configured in either Mass or Volume dosing mode. If this option is disabled, all drugs and protocols are computed in dose units of mass.

On all drug parameter screens except **DRUG** name, press **BACK** to return to the previous parameter.

1. Turn **LOCK 1** to **SET** position while pressing down button.
2. Enter the access code using the buttons.
3. Select **DRUG NAMES AND SAFETY LIMITS** from the menu. Press **ENTER.**



4. Press **MODIFY DRUG** to modify the drug summary. Use buttons to select desired values. When field is correct press **OK** to store the selection.



5. **NAME:** Use buttons to set highlighted letter. Press **NEXT** for next character (up to twelve letters). Press **OK** when complete.
6. **DOSE MODE:** Use buttons to change dose mode. Changing dose mode resets Drug parameters to defaults and also resets Protocols that use this drug. To change dose mode, press **CONFIRM**. Press **OK** when complete. **Note**: **DOSE MODE** will not be displayed if Mix Mass & Volume Modes is disabled in General Options.
7. **MIN DRUG CONC**: Use buttons to set minimum concentration. For volume mode, concentration can be set to **OFF,** the lowest value. Press **OK** when complete.
8. **MAX DRUG CONC**: Use buttons to set maximum concentration. Press **OK** when complete. If min Drug conc is set to **OFF**, this parameter does not appear.
9. **MIN LOCKOUT PERIOD:** Use buttons to set minimum lockout period. Press **OK** when complete.
10. **MAX LOCKOUT PERIOD:** Use buttons to set maximum lockout period. Press **OK** when complete.
11. **MIN PCA DOSE**: Use buttons to set minimum PCA dose. Press **OK** when complete.
12. **MAX PCA DOSE**: Use buttons to set maximum PCA dose. Press **OK** when complete.
13. **MAX CONTINUOUS**: Use buttons to set maximum continuous rate. Press **OK** when complete.
14. **MAX LOADING DOSE:** Use buttons to set maximum loading dose. Press **OK** when complete.
15. **MAX DOSE LIMIT:** Use buttons to set maximum dose limit. Press **OK** when complete.
16. **MAX CLINICIAN BOLUS:** Use buttons to set the maximum clinician bolus. Press **OK** when complete.
17. **NEXT DRUG** to display the next drug name and the safety limits. The ten pre-set drug protocols are identified as 1 to 10.
18. Press **QUIT** to exit and return to configuration menu.
19. When set-up is complete, turn **LOCK 1** to **OFF** position to save selection and to turn pump off**.**

Configured Options Record

General Options

Enter the pump-specific information for your records on a copy of this page.

Option	Range		Default	Setting
ICONS ON DISPLAY	YES/NO		NO	
PROTOCOLS IN USE	1 - 10		5	
MODIFY PROTOCOL	YES/NO		YES	
HANDSET MODE	A / B / C		A	
DELAYED CALLBACK	YES/NO		YES	
DISPLAY SLEEP	YES/NO		YES	
CHIRP LOW ALARMS	YES/NO		NO	
CONTINUOUS INFUSIONS	YES/NO		YES	
LOADING DOSES	YES/NO		YES	
MAX DOSE LIMITS	YES/NO		YES	
VARIABLE DOSE RATES	YES/NO		YES	
COMMS PUMP IDENTITY	000 - 127		001	
COMMS ENABLED	YES/NO		YES	
NURSE CALL	YES/NO		NO	
NURSE CALL INVERTED	YES/NO		NO	
CONTINUOUS PRINT	YES/NO		NO	
DEFAULT SYRINGE	BD PLASTIPAK IVAC TERUMO B. BRAUN OMNIFIX MONOJECT R.R PRONTO BD WORLDWIDE ONCE	FRESENIOUS INJECT. RAPIJECT PHARMA-JECT BD PRECISE BRAUN PERFUSOR* JANPOL* * with options kit fitted	BD PLASTIPAK	
LOCK SYRINGE TYPE	YES/NO		NO	
QUIET MODE	YES/NO		NO	
GENERIC DRUG ENABLED	YES/NO		YES	
MAX DOSE LIMIT ALARM	YES/NO		YES	
MIX MASS & VOL MODES	YES/NO		NO	

Syringe Type	Enabled
UNIVERSAL	
BRAUN PERFUSOR	
JANPOL	

Hospital Name	Serial No.	Software Version
Approved by	Configured by	
Date	Date	

Drugs and Protocols Record

Enter the pump-specific information for your records

Hospital/Institution: _____

Drug names and Safety Limits

Department/Ward: _____

Drug number	Mass Range	Volume Range	1	2	3	4	5	6	7	8	9	10
Drug Name (12 characters)												
Dose Mode	Mass	Volume										
Minimum Drug Concentration	1µg/ml - 99.9mg/m	Off, 1µg/ml - 99.9mg/ml										
Maximum Drug Concentration	1µg/ml - 99.9mg/ml	1µg/ml - 99.9mg/ml										
Minimum Lockout Period	0 - 180 minutes	0 - 180 minutes										
Maximum Lockout Period	0 - 180 minutes	0 - 180 minutes										
Minimum PCA Dose	0µg - 99.9mg	0.0ml - 99.9ml										
Maximum PCA Dose	0µg - 99.9mg	0.0ml - 99.9ml										
Maximum Continuous	0µg/h - 999.0mg/h	0.0ml/h - 35ml/h										
Maximum Loading Dose	0µg - 99.9mg	0.0ml - 99ml										
Maximum Max Limit	0µg - 999mg	0.0ml - 999ml										
Maximum Clinician Bolus	1µg - 99.9mg	0.1ml - 99.9ml										

Protocol Default Set Up

Protocol number	A	B	C	D	E	F	G	H	I	J
Drug Name										
Drug Concentration										
PCA Dose										
Lockout Period										
Occlusion Level										
Continuous										
Loading Dose										
Max Limit										
Limit Duration										
PCA Delivery										

Model: _____

Serial Number: _____ ***Configured by:*** _____ ***Date:*** _____

Software Version: _____ ***Approved by:*** _____ ***Date:*** _____

Specifications

CONCENTRATION RANGE:

1µg/ml - 999µg/ml in 1µg/ml steps

1.0mg/ml - 99.9mg/ml in 0.1mg/ml steps

VOLUME MODE:

Concentration can also be set OFF, in which case no mass data is displayed.

PCA DOSE RANGE:

Mass Mode:	0.0µg - 99 9µg in 1µg steps
	1mg - 99.9mg in 0.1mg steps
Volume Mode:	0.0ml - 99.9ml in 0.1ml steps

PCA DELIVERY RATE:

100ml/h max. STAT rate for 30ml, 50ml and 100ml syringes and 80ml/h for 20ml syringes.

(Option to set duration from 1 to 60 mins in 1 min steps to minimum rate of 0.1ml/h and maximum of the STAT rate).

RATE CONVERSION FACTOR:

When pump is programmed in Mass units the conversion factor is:- ml/h = (dose/concentration)/(time in minutes/60).

LOCKOUT INTERVAL:

0 - 180 minutes in 1 minute steps

LOADING DOSE RANGE:

Mass Mode:	0µg - 999µg in 1µg steps
	0.0mg - 99.9mg in 0.1mg steps (Delivered at STAT rate)
Volume Mode:	0.0ml - 99.9ml in 0.1ml steps

CONTINUOUS RATE RANGE:

Mass Mode:	0µg/h - 90µg/h in 10µg/h steps
	0.0mg/h - 999.0mg/h in 0.1mg/h steps
Volume Mode:	0.0ml/h - 35.0ml/h in 0.1ml/h steps.

MAX DOSE LIMIT:

Mass Mode:	off, 1µg - 999µg in 1µg steps
	1mg - 999mg in 1mg steps
Volume Mode:	off, 0.1ml to 999ml in 0.1ml steps

1 - 8 hours duration in 1 hour steps.

PURGE RATE:

100ml/h

SYSTEM ACCURACY:

Drive Linearity:	+/- 1%
Bolus:	+/- 0.05ml
Volumetric:	+/- 2% (nominal)

(Volumetric accuracy is +/-2% typical by volume at the STAT PCA rate and above when the pump is used with the recommended syringes. Differences in factors such as size and plunger force in compatible syringes can cause variations in accuracy and trumpet curves.)

Important:
System accuracy is +/-2% typical by volume as measured using the trumpet curve test method defined in EN60601-2-24:1998 at rates of 1.0ml/h and above when the pump is used with the recommended syringes. Differences in factors such as size and plunger force in compatible syringes can cause variations in accuracy and trumpet curves. Also see trumpet curves section.

Environmental Specifications -

Operating Temperature	**+10°C - +40°C**
Operating Relative Humidity	**30% - 75%**
Operating Atmospheric Pressure	**700hPa - 1060hPa**
Transport & Storage Temperature	**-20°C - +50°C**
Transport & Storage Relative Humidity	**5% - 95%**
Transport & Storage Atmospheric Pressure	**600hPa - 1060hPa**

OPERATION MODE:

Continuous

CRITICAL VOLUME:

The maximum over infusion which can occur in the event of a single fault condition is 0.8ml for 20ml, 30ml and 50ml syringes and 1.5ml for a 100ml syringe.

ALARM CONDITIONS:

Pressure Limit exceeded	Low Battery Warning
Drive Disengaged	Battery Exhausted
Syringe Almost Empty	Cover Open during operation
Syringe Empty	Hand-set Disconnected
Max Dose Limit (optionally alarmed)	Internal Malfunction
Nurse Attention/Call Back	Syringe Error

PUMPING PRESSURE / ALARM LEVEL:

375mmHg (nominal) default alarm level (L-4) with 11 user selectable alarm levels (L-0 to L-10). Syringes may limit below level 10.

(The maximum pressure that can be developed by the system at the maximum user selectable alarm level is 1100mmHg).

CLINICIAN OVER-RIDE:

Bolus or continuous infusion in **RUN** mode.

(User selectable from 1µg - 99.9mg or 0.1ml to 99.9ml (volume mode) bolus dose administered at the STAT rate (100ml/h) or over 1 to 180 minutes delivery period).

Modify PCA Protocol in **SET** mode.

(When option to disable **MODIFY PROTOCOL** has been selected).

BATTERY OPERATION:

6 hours operation from a fully charged battery at 5.0ml/h and 20°C under normal conditions.

BATTERY TYPE AND RECHARGE TIME:

Rechargeable sealed lead acid type. 10 hours from discharge to 80% charge, 24 hours from discharge to 100% charge.

EVENT HISTORY:

2000 events rolling memory.

MEMORY RETENTION:

All calibration and set up information will be retained in the pump memory for a minimum of 3 years.

BOLUS VOLUME ACCURACY:

The following table provides an indication of the accuracy with which a bolus infusion will be delivered. Test carried out as specified in IEC/EN60601-2-24.

Bolus Volume (ml)	Bolus Rate (ml/h)	No. of Samples	Max. Positive (%)	Max. Negative (%)	Mean (%)
0.1	100	25	12	-14	-5
2	100	25	2.5	0	1
5	100	25	1	0	0.8

Occlusion Pressure Limits

The following tables show the worst case values for line pressure, time to alarm and bolus volume that can be expected in the event of an occlusion when the IVAC® 50ml syringe and G40020B extension set are selected.

Alarm Level	Rate (ml/h)	Maximum Time to occlusion alarm (min:sec)	Nominal Occlusion Alarm Pressure (mmHg)	Maximum Infusion Pressure (mmHg)	Maximum Bolus Volume (ml)
0	1	2:00	0	50	0.1
1	1	8:00	92	110	0.2
2	1	20:00	184	220	0.3
3	1	33:00	276	330	0.5
4	1	52:00	368	450	0.7
5	1	65:00	460	560	0.9
6	1	85:00	552	670	1
7	1	102:00	664	780	1.2
8	1	120:00	736	890	1.6
9	1	140:00	828	1000	1.8
10	1	155:00	920	1100	2
0	5	1:00	0	50	0.1
1	5	2:00	92	110	0.2
2	5	5:00	184	220	0.3
3	5	7:00	276	330	0.5
4	5	10:00	368	450	0.7
5	5	12:00	460	560	0.9
6	5	15:00	552	670	1
7	5	17:00	644	780	1.2
8	5	20:00	736	890	1.6
9	5	24:00	828	1000	1.8
10	5	26:00	920	1100	2

Compatible Syringes

The pump is calibrated and labelled for use with single-use disposable Luer-lock syringes. Only use the size and type of syringe specified on the pump display. The full list of permitted syringe models is dependent on the software version of the pump.

Syringe Range	Syringe Type	20ml	30ml	50ml	100ml
UNIVERSAL	IVAC®			✓	✓
	BD Plastipak	✓	✓	✓	
	B Braun Omnifix	✓	✓	✓	
	Terumo	✓	✓	✓	
	Rapiject			✓	
	BD Worldwide	✓	✓	✓	
	BD Precise	✓		✓	
	Pharma-Ject			✓	
	Once			✓	
	Fresenius Injectomat			✓	
	Monoject*	✓	✓	✓	
	RR Pronto	✓	✓	✓	
BRAUN PERFUSOR	B Braun Perfusor			✓	
JANPOL	Janpol			✓	

* Ξ TYCO / Healthcare KENDALL - MONOJECT.

Compatible Extension Sets

The pump uses standard, single-use, disposable extension sets and syringes with Luer-lock connectors. The user is responsible for verifying the suitability of a product used if it is not recommended by Cardinal Health.

Standard Sets

G40015 Standard PVC Syringe Extension Set (150 cm).
Priming Volume: 2.6ml

G40020B Standard PVC Syringe Extension Set (200 cm).
Priming Volume: 1.5ml

G402EP Extension set, luer lock connectors. Kink resistant DEHP free PVC yellow striped tubing. Bore 1mm. Length 200cm.
Priming volume 1.6ml.

Light Protected Sets

G40215 Amber Polyethylene Syringe Extension Set (150 cm).
Priming Volume: 1.2ml

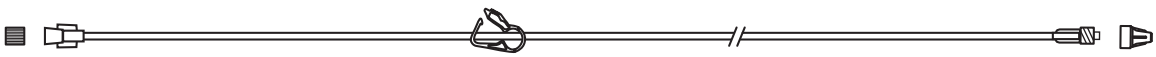
G40320 White PVC Syringe Extension Set (200 cm).
Priming Volume: 3.6ml

Low Sorbing Sets

G40615 Polyethylene Syringe Extension Set (150 cm).
Priming Volume: 1.5ml

G40620 Polyethylene Syringe Extension Set (200 cm).
Priming Volume: 2ml

G40720 Polyethylene Lined Syringe Extension Set with clamp. (200 cm).
Priming Volume: 1.5ml



04105010509 Polyethylene Syringe Extension Set (100 cm).
Priming Volume: 1ml

For availability please contact your local Cardinal Health representative because new sets are continuously being developed for our customers.

It is recommended that extension sets are changed in accordance with the Directions for Use.
Carefully read the Directions For Use supplied with the extension set prior to use.

Please note these drawings are not to scale

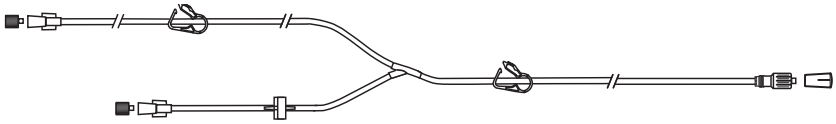
Compatible Extension Sets (Continued)

The pump uses standard, single-use, disposable extension sets and syringes with Luer-lock connectors. The user is responsible for verifying the suitability of a product used if it is not recommended by Cardinal Health.

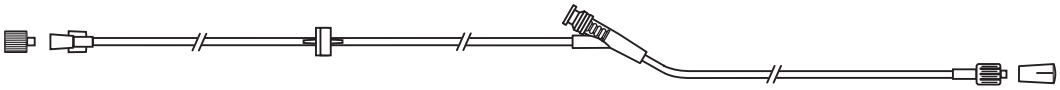
Patient Controlled Analgesia (PCA) Sets

30822 PVC Syringe Extension Set with clamp (152 cm).
Priming Volume: 0.5ml

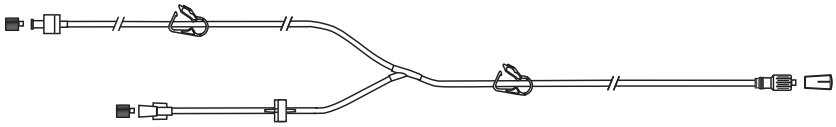
30832 PVC 'Y' Syringe Extension Set with back check valve and 2 clamps (178 cm).
Priming Volume: 1.5ml



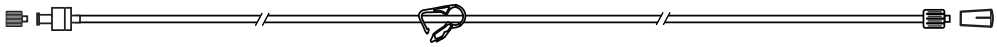
30842E PVC Syringe Extension Set with back check valve, SmartSite® Needle-Free Valve Port and clamp (30 cm).
Priming Volume: 1.4ml



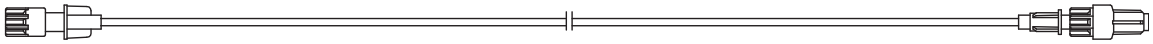
30852 PVC 'Y' Syringe Extension Set with anti-siphon valve, back check valve and 2 clamps (183 cm).
Priming Volume: 1.8ml



30862 PVC Syringe Extension Set with anti-siphon valve and clamp (156 cm).
Priming Volume: 0.6ml



04102215162 PVC Syringe Extension Set with rotating luer. (150 cm).
Priming Volume: 2.9ml



04100010162 PVC Syringe Extension Set (105 cm).
Priming Volume: 7.2ml

For availability please contact your local Cardinal Health representative because new sets are continuously being developed for our customers.

It is recommended that extension sets are changed in accordance with the Directions for Use.
Carefully read the Directions For Use supplied with the extension set prior to use.

Please note these drawings are not to scale

Maintenance

Routine Maintenance Procedures

To ensure that this pump remains in good operating condition, it is important to keep it clean and carry out the routine maintenance procedures described below. All servicing should only be performed by a qualified service engineer with reference to the Technical Service Manual (TSM).

Circuit diagrams and component parts lists and all other servicing information which will assist the qualified service engineer in performing repair of the parts designated as repairable are available upon request from Cardinal Health.

If the pump is dropped, damaged, subjected to excessive moisture or high temperature, immediately take it out of service for examination by a qualified service engineer.

All preventative and corrective maintenance and all such activities shall be performed at a compliant work place in accordance with the information supplied. Cardinal Health will not be responsible should any of these actions be performed outside the instructions or information supplied by Cardinal Health.

Refer to the Technical Service Manual for the access code for technical service features.

Interval	***Routine Maintenance Procedure***
As per Hospital Policy	Thoroughly clean external surfaces of the pump before and after prolonged period of storage.
At least once per year (Refer to TSM for identification of parts)	1. Inspect AC power supply plug and cable for damage. 2. Perform functional tests as outlined in the Technical Service Manual. 3. Operate the pump on battery power until the battery low alarm then charge the battery to confirm battery operation and charging.

Please refer to Technical Service Manual for calibration procedures. The units of measurement used in the calibration procedure are standard SI (The International System of Units) units.

Replacing the AC Fuses

If the pump continually illuminates the battery symbol and the AC power indicator light does not illuminate when the pump is connected to the AC power supply and switched ON, either the power supply fuse in the AC plug, if fitted, or the internal fuses have blown.

First check the power supply fuse in the AC mains plug, if fitted. If the AC power indicator light does not illuminate remove the pump from service.

It is recommended that only a qualified service engineer replaces the AC fuses. For further information regarding the replacement of internal AC fuses refer to the Technical Service Manual.

If the fuses continue to blow, suspect an electrical fault and have the pump and power supply checked out by a qualified service engineer.

Battery Operation

The internal rechargeable battery allows continued operation when the AC power is unavailable, for example during patient transfer or AC power failure. A fully charged battery will provide over 6 hours of operation at typical infusion rates. From the battery low alarm it will take about 24 hours to fully recharge when reconnected to the AC power supply, whether the pump is in use or not.

The battery is maintenance free, sealed lead acid type and requires no routine servicing. However, to achieve optimum operation, ensure that the battery is fully recharged after full discharge, before storage, and at regular 3 month intervals during storage.

Cardinal Health recommend verification that the pump operates on battery power once the pump has been removed from the AC power supply, refer to 'Starting the Pump' section.

Charge retention will eventually degrade. Where retention is critical the internal battery should be replaced every 3 years.

It is recommended that only a qualified service engineer replaces the battery. For further information regarding the replacement of batteries refer to the Technical Service Manual.

Test Routines

The test routines are designed to allow confirmation of many of the pump functions, defaults and calibrations without requiring internal inspection. They do not represent a full calibration check.

See the Technical Service Manual for a complete list of the test procedures, access codes and calibration procedures.

Maintenance (continued)

Cleaning and Storage

Before the transfer of the pump to a new patient and periodically during the use, clean the pump by wiping over with a lint-free cloth lightly dampened with warm water and a standard disinfectant / detergent solution.

Recommended cleaners are:

Brand	Concentration
Hibiscrub	20% (v/v)
Virkon	1% (w/v)

Do not use the following disinfectant types:

- Disinfectants which are known to be corrosive to metals must not be used, which include:
  - NaDcc (such as Presept),
  - Hypochlorites (such as Chlorasol),
  - Aldehydes (such as Cidex),
  - Cationic Surfactants (such as Benzalkonium Chloride).
- Use of Iodine (such as Betadine) will cause surface discoloration.
- Concentrated Isopropyl alcohol based cleaners will degrade plastic parts.

The syringe and extension sets are disposable single use items and should be discarded after use according to their manufacturers' instructions.

If the pump is to be stored for an extended period it should be first cleaned and the internal battery fully charged. Store in a clean, dry atmosphere at room temperature and, if available, employ the original packaging for protection.

Once every 3 months during storage, carry out functional tests as described in the Technical Service Manual and ensure that the internal battery is fully charged.

Before cleaning always switch OFF and disconnect from the AC power supply. Never allow liquid to enter the casing and avoid excess fluid build up on the pump. Do not use aggressive cleaning agents as these may damage the exterior surface of the pump. Do not steam autoclave, ethylene oxide sterilise or immerse this pump in any fluid.

Disposal

Information on Disposal for Users of Waste Electrical & Electronic Equipment

This  symbol on the product and/or accompanying documents means that used electrical and electronic products should not be mixed with municipal waste.

If you wish to discard electrical and electronic equipment, please contact your Cardinal Health affiliate office or distributor for further information.

Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

Information on Disposal in Countries outside the European Union

This symbol is only valid in the European Union. The product should be disposed of taking environmental factors into consideration. To ensure no risk or hazard, remove the internal rechargeable battery and the Lithium battery from the control board and dispose of as outlined by the local country regulations. All other components can be safely disposed of as per local regulations.

RS232 and Nurse Call Specification

RS232 / Nurse Call Feature

The RS232 / Nurse call feature is a feature on Alaris® Syringe Pumps. It allows the pump to be monitored remotely and/or controlled via a suitable central monitoring or computer system.

When the pump is started by a command from the serial interface, communication must take place over the serial interface. A communication must take place every 15 seconds or the pump will alarm, display communications failure and stop infusing. This failure protects against failure of the communications, including the removal of the RS232 cable.

The nurse call interface provides a remote backup to the internal audible alarm. It should not be relied upon to replace monitoring of the internal alarm.

Refer to the Technical Service Manual for further information regarding the RS232 interface. Since it is possible to control the syringe pump using the RS232 interface at some distance from the pump and hence remote from the patient, responsibility for the control of the pump is vested in the software run on the computer control system.

The assessment for the suitability of any software used in the clinical environment to control or receive data from the pump lies with the user of the equipment. This software should include detection of the disconnection or other failure of the RS232 cable. The protocol is detailed in the Technical Service Manual and is for general information only.

Any connected analogue and digital components are required to meet IEC/EN60950 for data processing and IEC/EN60601 for medical devices. Anyone connecting additional devices to the signal input or output is a system configurator and responsible for meeting the requirements of the system standard IEC/EN60601-1-1.

RS232 / Nurse Call Connection Data

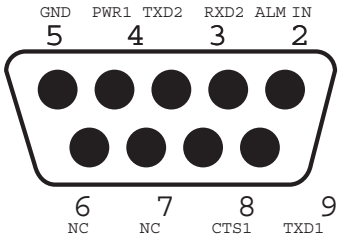
Nurse call Specification -

Connector	D Type - 9 Pin
TXD/RXD	EIA RS232-C Standard
TXD Output Voltage Range	Minimum: -5V (mark), +5V (space) Typical: -7V (mark), +7V (space) with 3KΩ load to ground
RXD Input Voltage Range	-15V to +15V max.
RXD Input Thresholds	Low: 0.6V minimum / High: 3.0V maximum
RXD Input Resistance	3KΩ minimum
Isolation Socket/Pump	4kV (dc, or ac peak)
Baud Rate	9600 Baud
Start Bits	1 Start Bit
Data Bits	8 Data Bits
Parity	Odd Parity
Stop Bits	1 stop bit
Nurse Call Relay Contacts	Pins 6 & 7

IBM COMPATIBLE (9 PIN)		PUMP		IBM COMPATIBLE (25 PIN)
PIN 3 (TXD)	———	PIN 2 (RXD2)	———	PIN 2 (TXD)
PIN 2 (RXD)	———	PIN 3 (TXD2)	———	PIN 3 (RXD)
PIN 5 (GND)	———	PIN 5 (GND)	———	PIN 7 (GND)
PIN 7 (RTS)	⌐		⌐	PIN 4 (RTS)
PIN 8 (CTS)	———		———	PIN 5 (CTS)
PIN 4 (DTR)	⌐		⌐	PIN 20 (DTR)
PIN 6 (DSR)	———		———	PIN 6 (DSR)

	PUMP	
	PIN 1 (ALM1)	RESP ALARM

	PUMP	PRINTER (25 PIN)
	PIN 9 (TXD1)	PIN 3 (RX)
	PIN 4 (PWR1)	PIN 5 (CTS)
	PIN 5 (GND)	PIN 7 (GND)
	PIN 8 (CTS1)	PIN 20 (DTR)



Trumpet Curves & Start-up Curves

In this pump, as with all infusion systems, the action of the pumping mechanism and variations in individual syringes cause short-term fluctuations in rate accuracy.

The following curves show typical performance of the system in two ways: 1) the delay in onset of fluid flow when infusion commences (start-up curves), and 2) the accuracy of fluid delivery over various time periods is measured (trumpet curves).

The start-up curves represent continuous flow versus operating time from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Tests performed per IEC/EN60601-2-24 standard.

Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or 'observation windows', not continuous data versus operating time. Over long observation windows, short term fluctuations have little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short term fluctuations have greater effects as represented by the "mouth" of the trumpet.

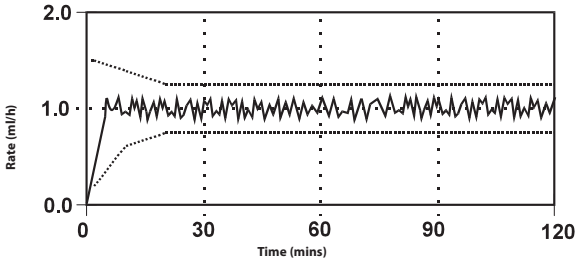
Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short term fluctuations in rate accuracy may have clinical impact depending on the half-life of the drug being infused, therefore the clinical effect cannot be determined from the trumpet curves alone.

Start-up and trumpet curves may not be indicative of operation under negative pressure.

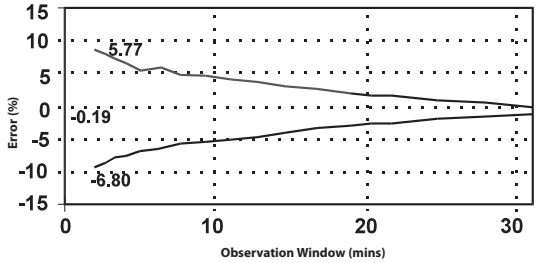
Differences in factors such as size and plunger force in compatible syringes produced by other manufacturers can cause variations in accuracy and trumpet curves as compared to those represented. Additional curves for compatible syringes are available upon written request.

For applications where flow uniformity is a concern, rates of 1.0 ml/h or above are recommended.

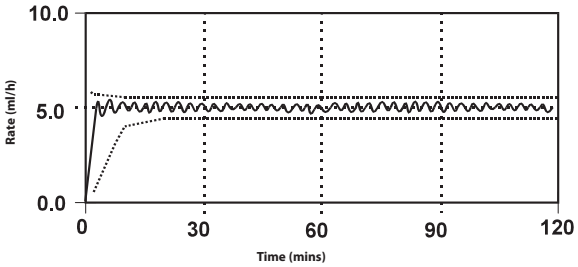
Start-up Trend. BD Plastipak 50ml @ 1.0ml/h



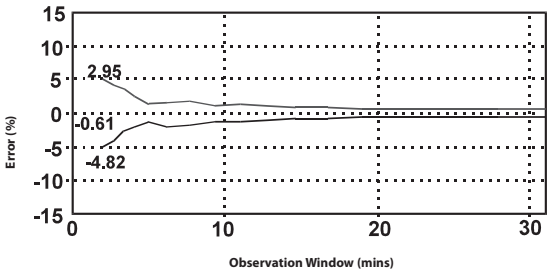
Trumpet Curve. BD Plastipak 50ml @ 1.0ml/h



Start-up Trend. BD Plastipak 50 ml @ 5.0 ml/h

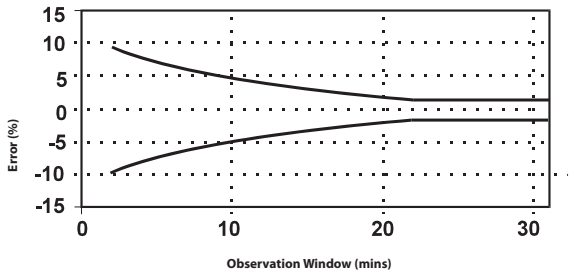


Trumpet Curve. BD Plastipak 50 ml @ 5.0 ml/h

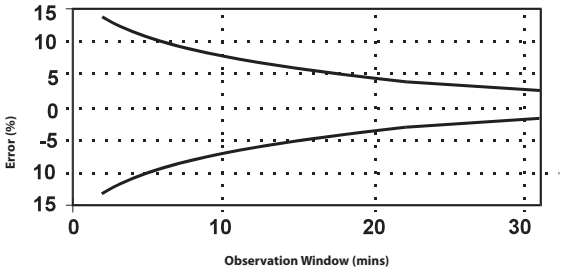


Trumpet curve values show minimum and maximum percentage rate error at 2 minutes and long term accuracy.

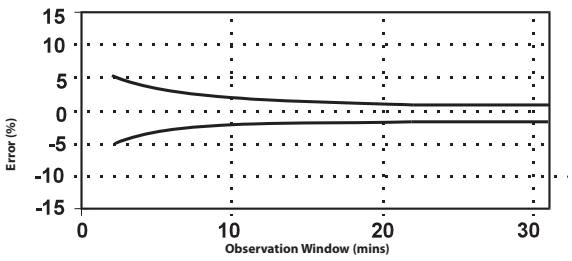
Trumpet Curve @ 1.0 ml/h



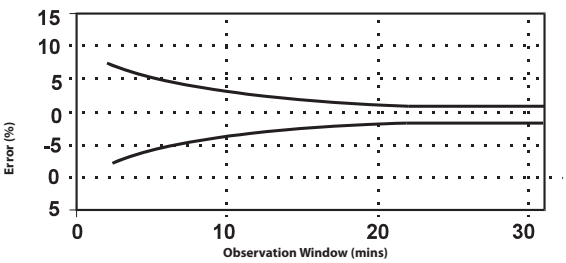
Trumpet Curve @ 1.0 ml/h



Trumpet Curve @ 5.0 ml/h



Trumpet Curve @ 5.0 ml/h



Performance with syringes : BD Plastipak, B Braun Omnifix, Monoject, Once. 2 minute minimum/maximum +/- 5% @ 5.0ml/h. Long term mean accuracy +/- 2% is in addition to the trumpet curve percentage error.

Performance with syringes : IVAC, Zeneca, Terumo, Nipro, Fresenius, B Braun Perfusor & JMS. 2 minute minimum/maximum +/- 7.5% @ 5.0ml/h. Long term mean accuracy +/- 2% is in addition to the trumpet curve percentage error.

Evaluation over the range -100mmHg to +100mmHg equivalent to water height +/- 1.3m, will produce trumpet curves with the limits shown above.

Service Contacts

For service contact your local Affiliate Office or Distributor.

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Document History

Revision	*CO Number*	*Date*
1	6921	July 06
2	7751	July 07
3	8700	July 08
4	8853	October 08
5	9116	January 09

Spare Parts

A comprehensive list of spare parts for this pump is included within the Technical Service Manual.

The Technical Service Manual (1000SM00017) is now available in electronic format on the World Wide Web at :-

www.cardinalhealth.com/alaris

A username and password are required to access our manuals. Please contact local customer services representative to obtain login details.

Part Number	Description
0000EL00004	Internal Battery Pack
1001FAOPT91	AC Power Lead - UK
1001FAOPT92	AC Power Lead - European
5000SP00008	Printer cable 9 to 25 pin
5000SP00011	Printer cable 9 to 26 pin
1000SP01008	Comms Cable (9 pin to 9 pin)
1000SP01015	Pole Clamp Assembly

Cardinal Health, Alaris® Products ("Cardinal Health") warrants that:

(A) Each new infusion instrument (pump, controller or peripheral instrument) is free from defects in material and workmanship under normal use and service for a period of two (2) years from the date of delivery by Cardinal Health to the original purchaser.

(B) Each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Cardinal Health to the original purchaser.

(C) Each Mains Cable, Battery, Flow Sensor (ECD) and non-disposable probe is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Cardinal Health to the original purchaser.

(D) Each new Thermometer is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by Cardinal Health to the original purchaser.

If any product requires repair during the applicable warranty period, the purchaser should communicate directly with its local Cardinal Health service centre to determine the appropriate service facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at Cardinal Health's expense. The product requiring service should be returned promptly, properly packaged, and postage prepaid by purchaser. Loss or damage in return shipment to Cardinal Health shall be at purchaser's risk.

In no event shall Cardinal Health be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Cardinal Health product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product.

Furthermore, this warranty shall not apply to, and Cardinal Health shall not be responsible for, any loss or damage arising in connection with the purchase or use of any Cardinal Health product which has been:

(A) repaired by anyone other than an authorised Cardinal Health service representative;

(B) altered in any way so as to affect, in Cardinal Health's judgement the stability or reliability of the product or has had the product's serial or lot number altered, effaced or removed;

(C) subjected to misuse or negligence or accident; or

(D) improperly maintained or used in any manner other than in accordance with the written instructions furnished by Cardinal Health.

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